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EXAMINER	
HORNBERGER, JENNIFER LEA	
ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
08/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/586,011	JORGENSEN ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 36-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 36-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07/14/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 62 is objected to because of the following informalities: Claim 62 depends from canceled claim 26. Appropriate correction is required.

Double Patenting

2. Applicant is advised that should claim 1 be found allowable, claim 36 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 55, 62, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 55 provide for the use of a catheter according to claim 36 for performing angioplasty, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

4. Claims 62 provides for the use of a catheter according to claim 26 for performing angioplasty, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite

where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

5. Claims 69 provides for the use of a catheter according to claim 40 for performing angioplasty, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 55, 62, and 69 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 36-40, 44, 45, 50-56, 60-63, and 67-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Loaldi (US 2003/0187494).

Regarding claims 1 and 36, Loaldi discloses a balloon catheter for positioning of a stent in coronary or peripheral angioplasty, the catheter comprising a hollow conduit with an open proximal end and a closed distal end forming exactly one expandable section (5) with an outer surface part adapted to hold a stent and having no bifurcations or side openings, one or more guidewire lumens (12,13) or grooves to provide passage for two or more guidewires inside an outer perimeter of the expandable section (Fig. 3, 6B, 18-25).

Regarding claim 37, Loaldi discloses at least one guidewire lumen (12, 13) provides passage for two or more guidewires inside said outer surface part of the hollow conduit from at least one open end part (16, 17) of the at least one guidewire lumen (12, 13) proximal to said outer surface part (5) and through the closed end of the hollow conduit distal to said outer surface part (14, 15; Fig. 3, 6B, 18-25).

Regarding claim 38, Loaldi discloses the catheter is an over-the- wire or a rapid exchange type catheter (Fig. 3, 6B, 24, 25).

Regarding claim 39, Loaldi discloses a balloon catheter for positioning of a stent in coronary or peripheral angioplasty, the catheter comprising a hollow conduit with an open proximal end and a closed distal end forming an expandable section (5) for holding and expanding a stent, the balloon catheter being characterised in that it comprises exactly one expandable section, it further comprises one or more guidewire lumens (12, 13) or grooves extending along at least part of the expandable section and providing passage for at least two guidewires inside the expandable section so that, after expansion of a stent by the expandable section, the at least two guidewires run through the stent from end to end, and in that the expandable section has an outer perimeter with no bifurcations or side openings (Fig. 3, 6B, 18-25).

Regarding claim 40, Loaldi discloses a balloon catheter for positioning of a stent in coronary or peripheral angioplasty, the catheter comprising a hollow conduit with an open proximal end and a closed distal end forming an expandable section (5) for holding and expanding a stent, the balloon catheter being characterised in that it comprises exactly one expandable section, it further comprises one or more guidewire lumens (12, 13) or grooves extending along at least part of the expandable section and providing passage for at least two guidewires inside the expandable section so that, after expansion of a stent by the expandable section, the at least two guidewires pass through the stent from end to end, and in that it is adapted to position the stent in a principal vessel proximal to the bifurcation without entering either branch distal to the bifurcation with the expandable section (Fig. 3, 6B, 18-25).

Regarding claims 44, 60, and 67, Loaldi discloses said one or more guidewire lumen(s) extend(s) beyond an extreme distal end of the expandable section and is divided into two or more individual guidewire lumens at a position of exit from the extreme distal end of the expandable section (paragraph 139. Fig. 28, 29)

Regarding claims 45, 61, and 68, Loaldi discloses an assembled stent delivery system comprising a balloon catheter of claim 36, and a stent (6) held by the expandable section of the hollow conduit so that the one or more guidewire lumen(s) or groove(s) provide(s) inlets (14,15) and outlets (16, 17) for two or more guidewires distally and proximally to the stent (Fig. 3, 6B, 18-25).

Regarding claim 50, Loaldi discloses a method for positioning a stent in a principal vessel proximally to a bifurcation, the method comprising the steps of: inserting a distal end of a first guidewire through the principal vessel and into a first branch of the bifurcation, inserting a distal end of a second guidewire through the principal vessel and into a second branch of the bifurcation (paragraph 114; Fig. 18), providing a first catheter for positioning of a first

expandable stent mounted on a distal end section of the catheter, the first catheter comprising one or more guidewire lumen(s) providing passage for two or more wires through the stent from end to end, threading the one or more guidewire lumen(s) with proximal ends of the first and the second wire, advancing the first catheter simultaneously over the first and the second wire until the first stent reaches the principal vessel proximal to the bifurcation, and expanding the first stent (paragraphs 115-118; Fig. 19 and 20).

Regarding claim 51, Loaldi discloses a method for positioning stents at a bifurcation of an artery and in a principal vessel proximally to the bifurcation, the method comprising positioning a stent in the principal vessel proximally to the bifurcation according to claim 50, the method further comprising the steps of: withdrawing the first catheter simultaneously over the first and the second wire (paragraph 119),
threading and advancing a second catheter mounted with a second expandable stent over the first guidewire and at least partially into the first branch of the bifurcation, and
expanding the second stent of the second catheter (paragraphs 120, 122, and 123).

Regarding claim 52, Loaldi discloses the step of advancing the second catheter comprises advancing the second catheter so that a distal end of the second stent is positioned in the first branch of the bifurcation and a proximal end is positioned inside the first stent (paragraph 122).

Regarding claim 53, Loaldi discloses threading and advancing a third catheter mounted with a third expandable stent over the second guidewire and at least partially into the second branch of the bifurcation, and expanding the third stent of the third catheter (paragraphs 121, 122, and 123).

Regarding claim 54, Loaldi discloses advancing the third catheter comprises advancing the third catheter so that a distal end of the third stent is positioned in the second branch of the bifurcation and a proximal end is positioned inside the first stent (paragraph 122).

Regarding claims 55, 56, 62, 63, 69, and 70, the catheter is capable of being used for coronary angioplasty.

8. Claims 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Vardi et al. (US 2001/0003161).

Regarding claim 46, Vardi et al. disclose an assembled stent delivery system comprising two or more balloon catheters (12, 20) extending in parallel to each other and a stent (25) held by and circumventing an expandable section of a first balloon (11) catheter and a non-expandable section of a second balloon catheter (20), the system thereby providing passage for two or more guidewires (21, 31) through the stent (Fig. 4-5).

Regarding claim 47, Vardi et al. disclose the catheters are over-the-wire and/or rapid exchange type catheters.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 41-43, 57-59, and 64-66 rejected under 35 U.S.C. 103(a) as being unpatentable over Loaldi (US 2003/0187494). Loaldi discloses the expandable section comprises a cylindrical central section for holding a stent, but fails to disclose the distance from the distal end of the cylindrical central section to an inlet of a first guidewire lumen or groove. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine

the optimum distance between the distal end of the cylindrical central section and the inlet of the first guidewire lumen, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

11. Claims 48 and 49 rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (US 2001/0003161) in view of Shaknovich (US 5,669,924). Vardi et al. fail to disclose the stent is biodegradable or coated with one or more anti proliferative medical agents. Shaknovich discloses coating the stent with a biodegradable polymer layer with antiproliferative properties to prevent restenosis (col. 13, ln. 7-32). It would have been obvious to one of ordinary skill in the art to modify the stent of Vardi et al. to comprise a biodegradable layer having antiproliferative properties in order to prevent restenosis at the treatment site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
08/03/2009

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734